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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,565	08/09/2001	Preeti Lal	PF-0450-1 DIV	6831

27904 7590 09/25/2003

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,565	LAL ET AL.	
	Examiner	Art Unit	
	Robert Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on th cover she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-4**, drawn to an isolated polypeptide and compositions comprising same, classified in class 530, subclass 300, for example.

II. Claim **5**, drawn to a method for using a polypeptide to screen a plurality of molecules in a sample to identify and purify an agonist, classification dependent upon agent structure.

III. Claims **6 and 7**, drawn to an agonist and compositions comprising same, classification dependent upon agent structure.

IV. Claim **8**, drawn to a method for using a polypeptide to screen a plurality of molecules in a sample to identify and purify an antagonist, classification dependent upon agent structure.

V. Claims **9 and 10**, drawn to an antagonist and compositions comprising same, classification dependent upon agent structure.

VI. Claim **11**, drawn to a method for using a polypeptide to screen a plurality of molecules in a sample to identify a compound which specifically binds said polypeptide, classification dependent upon agent structure.

VII. Claim **12**, drawn to a method for using a polypeptide to screen a plurality of molecules in a sample to identify a compound which modulates the activity of said polypeptide, classification dependent upon agent structure.

VIII. Claims **13 and 14**, drawn to a compound which modulates the activity of a polypeptide, classification dependent upon agent structure.

IX. Claims **15-20**, drawn to a method of using a polypeptide to prepare antibodies, antibodies, and compositions comprising same, classified in class 530, subclass 387.1, for example.

X. Claims **21**, drawn to a method for recombinant production of a polypeptide, classified in class 435, subclass 69.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions II, IV, VI, VII, IX, and X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention II requires search and consideration of identifying and purifying an agonist, which is not required by any of the other Inventions. Invention IV requires search and consideration of identifying and purifying an antagonist, which is not required by any of the other Inventions. Invention VI requires search and consideration of identifying a compound that specifically binds a polypeptide, which is not required by any of the other Inventions. Invention VII requires search and consideration of identifying a compound which modulates the activity of a polypeptide, which is not required by any of the other Inventions. Invention IX requires search and consideration of making antibodies, which is not required by any of the other Inventions.

Invention X requires search and consideration of recombinant production of a polypeptide, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, III, V, and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

5. The polypeptide of Invention I can be prepared by processes which are materially different from the agonist of Invention III, the antagonist of Invention V, and the compound of Invention VIII, such as by chemical synthesis, or by isolation and purification from natural sources.

6. The antagonist of Invention V and the compound of Invention VIII are not required to make or use the agonist of Invention III. Although the polypeptide of Invention I can be used to isolate the agonist of Invention III, it can be made through materially different methods such as chemical synthesis or purification from natural sources.

7. The agonist of Invention III and the compound of Invention VIII are not required to make or use the antagonist of Invention V. Although the polypeptide of Invention I can be used to isolate the antagonist of Invention V, it can be made through materially different methods such as chemical synthesis or purification from natural sources.

8. The agonist of Invention III and the antagonist of Invention V are not required to make or use the compound of Invention VIII. Although the polypeptide of Invention I can be used to

isolate the compound of Invention VIII, it can be made through materially different methods such as chemical synthesis or purification from natural sources.

9. Inventions I and each of II, IV, VI, VII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention I could be used in a materially different method such as therapeutic methods,

10. Inventions II and each of III and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds of Inventions III and VII could be made through materially different methods such as chemical synthesis or purification from natural sources.

11. Inventions IV and each of V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds of Inventions V and VII could be made through materially different methods such as chemical synthesis or purification from natural sources.

12. Inventions VII and each of III, V, and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds of Inventions III, V, and VII could be made through materially different methods such as chemical synthesis or purification from natural sources.

13. Inventions X and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention I could be made through materially different methods such as chemical synthesis or purification from natural sources.

14. Inventions III and each of IV, VI, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of IV, VI, IX, and X are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IV, VI, IX, and X do not recite the use or production of the agonist of Invention III.

15. Inventions V and each of II, VI, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions V and each of II, VI, IX, and X are unrelated product and methods, wherein each is not required, one for another. For example, the

claimed methods of Inventions II, VI, IX, and X do not recite the use or production of the antagonist of Invention V.

16. Inventions VIII and each of VI, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and each of VI, IX, and X are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI, IX, and X do not recite the use or production of the compound of Invention VIII.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Robert Hayes, Ph.D.** whose telephone number is **(703) 305-3132.** The examiner can normally be reached on Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary d. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

CJN
September 23, 2003